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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,299	05/31/2006	Kazutoshi Watanabe	P28460	1935

7055	7590	09/18/2007
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EXAMINER	
BALASUBRAMANIAN, VENKATARAMAN	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
09/18/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/550,299	Applicant(s) WATANABE ET AL.	
	Examiner /Venkataraman Balasubramanian/	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11,13,14 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11,13,14 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicants' response, which included cancellation of claims 12, 15 and amendment to claims 1, 13, 14 and 16, filed 9/4/2007 under 37 CFR 1.116 in reply to the final rejection has been made of record.

In view of applicants' response, the 112 first paragraph rejection, 103 rejection and obviousness double patenting rejections made in the previous office action have been obviated. However, upon further consideration, the Finality of the previous office action is vacated and the following new grounds of rejections are applied to currently pending claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11, 13, 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Recitation "m= 1 to 3" and "n= 0-8" in claim 1, which amounts to maximum substituents of 11 in the piperazine or piperidine ring, renders claim 1 and its dependent claims 2-9, 11, 13, 14 and 16 indefinite as it is not clear how piperazine or piperidine accommodate a maximum substituents of 11 when only 9 and 10 positions are available in each of these rings. If nitrogen is permitted to be substituted then there should be charge on the nitrogen and a counter ion.

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2. Recitation of "when ring represented by X or X¹" in claim 1 renders claim 1 and its dependent claims 2-9, 11, 13, 14 and 16 indefinite as it is not clear what is intended. As recited X and X¹ are independent variables which is not the case. Note $X = X^1 - X^2$ wherein X¹ is a ring bearing substituents. Therefore X and X¹ are not independent variables.

3. Recitation "Z= N or C-Z¹ and Z¹ is H or Y" renders claim 2 and its dependent claims 3-9 indefinite as it is not clear what is the structural make-up of the compound based on said choices. Note when Z= N, q = 0 as permitted in the claim, the trivalent nitrogen will be divalent with one valence requirement not met with or met with undefined group. The same is true when Z=C-H or C-Y. The tetravalent carbon will be trivalent carbon with one valence requirement not met with or met with undefined group. Alternatively, if one were assume that q= 1, that is X is always present then p is always zero. Thus, the variation p=1 is never possible and hence it is not clear why claims 2-9 permit X choice in the other position of the ring other than Z position.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 8, 9 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Almario-Garcia et al., WO 01/70728 in view of Almario-Garcia et al., EP 1136482(equivalent US 6,844,335).

The primary reference, Almario-Garcia et al., teaches a genus of 4-pyrimidone compounds of formula I, composition and method of use, which include instant compounds, composition and method of use. See page 5, formula 1 and note the definition of X, Y, R1 and R2. See pages 5-16 for details of the invention including preferred embodiments, species and method of making. See pages 18-25 including Table 1-3, for various compounds made. Especially see Also See Table 1 and Table 2 for various piperazine and piperidone compounds made.

Almario-Garcia et al., differs from the instant claims in exemplifying compounds wherein the nitrogen of the pyrimidine ring has hydrogen instead of alkyl as required by instant claims. That is instant R is C₁-C₁₂ alkyl while Almario-Garcia et al., teaches only hydrogen in that position.

The secondary reference Almario-Garcia et al., EP 1136482 (EP), teaches a genus of 4-pyrimidone compounds of formula I, composition and method of use, which include generically instant compounds, composition and method of use. See formula 1 and note when R¹ and R² form a ring as permitted by the reference, the compounds taught by Almario-Garcia include instant compounds. See Table 1 for various compounds made. See compound 38 and 39.

Almario-Garcia et al.,(EP) differs from the instant claims in not exemplifying compounds wherein ring formed with R¹ and R² taken together having substituents. That is compound 38 and 39 lack instant X substituents. But, Almario-Garcia et al., (EP) clearly teaches an alkyl on the second nitrogen of the pyrimidine as required by the instant claims for R choice. In other words, the primary reference teaches all the elements of the instant claims except the instant R choice, while the secondary reference teaches such R choices. Thus, one trained in the art would be motivated to combine the teachings of the primary reference and the secondary reference and expect the resultant compound (instant compound) to have the same use as taught in these references in view of combined equivalency teaching of active compounds with H and alkyl as substituents on second nitrogen of the pyrimidone.

See In re KSR International vs. Teleflex Inc., 82 USPQ2d 13-85, 1397 (2007).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 13, 14, and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,44,335 in view of WO 01/70728. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound and composition embraced in the instant claims overlaps with the method of use embraced in claims 1-50 of US 6,844,335. Note claim 1 of the US patent relates to compounds wherein R¹ and R² form a ring, which can further substituted. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds wherein R¹ and R² form a ring with substituents using the teachings of US 6,844,335 and expect resulting compounds to possess the uses taught by the art

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in view of the equivalency teaching outline above. The secondary references clearly shows as discussed in the above 103 rejection various substituents in the said ring. Thus, one trained in the art would be motivated to make compounds generically taught in claim 1 with various substituents including those positively exemplified in the WIPO document and expect the resultant compound to have the use taught therein.

Claims 1-11, 13, 14 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 16-24, 31-39 and 41-45 of copending Application No. 11/035,264 in view of WO 01/70728. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims is also embraced in the copending application. Note when R^3 is pyridyl and X is N, compounds, composition and method of use embraced in the copending application overlap with those of instant claims.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds wherein R^1 and R^2 form a ring using the teachings of 11/035,264 and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

The secondary references clearly shows as discussed in the above 103 rejection various substituents in the said ring. Thus, one trained in the art would be motivated to make compounds generically taught in claims 1-5, 7, 16-24, 31-39 and 41-45 of copending Application No. 11/035,264 with various substituents including those

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positively exemplified in the WIPO document and expect the resultant compound to have the use taught therein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

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